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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,063	08/22/2003	Martin H. Teicher	04843/113003	8435
21559	7590	03/31/2005	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			CORDERO GARCIA, MARCELA M	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/646,063

Applicant(s)

TEICHER ET AL.

Examiner

Marcela M Cordero Garcia

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-15 and 19-28 is/are pending in the application.
- 4a) Of the above claim(s) 14, 16-18 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 13, 15, 19, 20, 21, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election without traverse of Group II, claims 12-15 and 19-28 and of the species polyguanidyl conjugate of Example 3, the structure of which is provided on page 30 of the specification, for the treatment of rheumatoid arthritis in the reply filed on February 25, 2005 is acknowledged.

The species was searched and found free of the prior art.

The examiner elected a new species: dextran-methylprednisolone succinate as in Scheme I, page 2079 of Zhang et al. (J Pharm Sci, 2001) for the treatment of organ/tissue transplant rejection. Claims 12, 13, 15, 19, 20, 21, 22 and 23 are readable thereon.

Claims 12, 13, 15, 19, 20, 21, 22 and 23 are presented for examination on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 13, 15, 19, 20, 21, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (J Pharm Sci, 2001).

Zhang et al. teach a method of treating an autoimmune or inflammatory condition in a mammal, said method comprising administering to said mammal a corticosteroid

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conjugate comprising a corticosteroid attached to a group that is either a bulky group of greater than 400 daltons or a charged group of less than 400 daltons in an amount effective to treat said condition, wherein said corticosteroid conjugate has anti-inflammatory activity in vivo and reduced activity in the central nervous system in comparison to said corticosteroid without said group (see entire document, e.g., abstract and column 1, paragraph 1, page 2079, Scheme I, page 2079 and pages 2085-2086).

Therefore, the reference is deemed to anticipate the instant claims above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 13, 15, 19 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (J Pharm Sci, 2001).

Zhang et al. beneficially teach a method of treating an autoimmune or inflammatory condition in a mammal, said method comprising administering to said

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mammal a corticosteroid conjugate comprising a corticosteroid attached to a group that is either a bulky group of greater than 400 daltons or a charged group of less than 400 daltons in an amount effective to treat said condition, wherein said corticosteroid conjugate has anti-inflammatory activity in vivo and reduced activity in the central nervous system in comparison to said corticosteroid without said group (see e.g., Scheme I, abstract and column 1, paragraph 1, page 2079, and pages 2085-2086).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust particular conventional working conditions within such a therapeutic method (e.g., using different modes of administration) based upon the overall beneficial teachings provided by Zhang et al. These types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claim is allowed.


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Marcela M Cordero Garcia, Ph.D.  
Patent Examiner  
Art Unit 1654

MMCG 03/05

  
CHRISTOPHER R. TATE  
PRIMARY EXAMINER